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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,183	09/18/2006	Hiroko Inomata	0649-1340PUS1	8800
2292 7590 08/19/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER WHISENANT, ETHAN C				
ART UNIT		PAPER NUMBER		
1634				
NOTIFICATION DATE		DELIVERY MODE		
08/19/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/593,183

Applicant(s)

INOMATA ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 1-18 is/are allowed.
6) ☒ Claim(s) 19-43 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

NON-FINAL ACTION

1. The applicant's Preliminary Amendment filed 18 SEP 06 has been entered. Following the entry of the Preliminary Amendment, **Claim(s) 1-43** is/are pending.

35 USC § 112- 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 20-43** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-21 and 43 are indefinite because it is unclear what structural limitation(s) is/are imparted by the limitation "automatically". Please clarify.

Claim 22 is indefinite because there is no nexus between the preamble and the claim steps. Claim 22 in its preamble direct to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

Claims 31 is indefinite in that it is unclear what is intended by the word "separeting". Also, the preamble recites only RNA and not DNA or RNA as set forth in

Claims 22 and 28 (i.e. the claims from which Claim 31 depends) therefore the exact scope encompassed by Claim 31 is ambiguous.

35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

CLAIM REJECTIONS UNDER 35 USC § 102

6. **Claim(s) 22-25, 28-30, 32-41** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Mori et al. [US 2003/0170664(2003)].

Mori et al. teach a method of purifying nucleic acids (i.e. RNA or DNA) which comprises all of the limitations recited in Claims 22-25, 28-30 and 32-41. As regards the composition of the washing buffer used by Mori et al. see especially paragraph [0088].

35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim Rejections under 35 USC § 103

9. Claim(s) 31 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al.[US 2003/0170664(2003)].

Claim 31 is drawn to an embodiment of the method of Claim 28 wherein the test sample is homogenized before or after adding the nucleic acid solubilizing reagent.

Mori et al. teach a method of purifying nucleic acids which comprises all of the limitations recited in Claim 31 except Mori et al. do not teach homogenization of the solution comprising the test cells before or after adding the nucleic acid solubilizing reagent. However, homogenization of a solution comprising the test cells before or after adding the nucleic acid solubilizing reagent was routine in the art, particularly when the target nucleic acid is a RNA molecule (Official Notice). Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the method of Mori et al. wherein a homogenization step is included. The ordinary artisan would have been motivated to modify Mori et al. as recited above in order to insure the complete release of the nucleic acids from the cells present in the test sample.

10. Claim(s) 19-21, 42-43 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al.[US 2003 /0170664(2003)] in view of the Stratagene Catalog [p.39 (1988)].

Claim 19 is drawn to kit comprising a cartridge and a reagent for performing the method recited in Claim 1. **Claim 42** is drawn to kit comprising a cartridge and a reagent for performing the method recited in Claim 22.

Mori et al. teach a cartridge capable of performing the method(s) recited in Claim 1 and 22. Mori et al. do not teach placing their cartridge in a kit along with a reagent(s) necessary to carry out the method recited in Claims 1 or 22. However, as evidenced by

the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the teachings Mori et al with the teachings of the Stratagene Catalog wherein the cartridge and reagents necessary to perform the method taught by Mori et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

REASON FOR ALLOWANCE

11. Claims 1-18 are allowable over the prior art of record. Independent Claim 1 is allowable over the prior art of record because none of the references of record alone teach all of the limitations recited in Claim 1. Neither does the prior art of record, in any combination, reasonably suggest the method(s) recited in independent Claim 1.

CONCLUSION

12. Claim(s) 1-18 is/are allowable while **Claim(s) 19-43** is/are rejected and/or objected to for the reason(s) set forth above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634

EXAMINER SEARCH NOTES

12 AUG 08 - ECW

Databases searched: USPATFULL, USPG-PUBS, JPIO and EUROPATFULL via EAST &

CAplus, Medline and BIOSIS via STN

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s) : e.g. Inomata H?/au

RNA or DNA or Nucleic
isolation or purification
cartridge\$ or column\$
adsorb\$
membrane\$
hydroxyl group\$
DNase\$ or Rnase\$
Wash\$
Chaotropic
Guanidine
Kit\$
Acetyl cellulose\$